Notice of Allowability	Application No.	Applicant(s)	
	10/645,312	YOON ET AL.	
	Examiner	Art Unit	
	Zachary C. Tucker	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *9 November 2005*.

2. ☒ The allowed claim(s) is/are *1,2,5-15,17-19 and 26*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone conversation between the examiner and applicants' counsel, Dwight D. Kim, on 22 November 2005.

IN THE CLAIMS –

Claims 16 and 20-25 have been cancelled.

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

end of amendment

Response to Amendments

The claims and abstract have been amended as requested in the correspondences from applicants, filed 4 October and 9 November 2005, which were in response to the Office action mailed 6 July 2005 (hereinafter "previous Office action").

Election/Restrictions

Groups I and II, as were set forth in the portion devoted thereto of the Official action mailed 6 July 2005, are hereby rejoined and the Requirement for Restriction between those two Groups is WITHDRAWN.

Status of Claim Rejections - 35 USC § 112

In the previous Office action, claims 12-14 were rejected under the second paragraph of this statute for indefiniteness of the term "a standard in vitro CRF binding assay." Applicants' argument in the correspondence filed 4 October 2005 is persuasive in overcoming the rejection. As is pointed out in the argument traversing the indefiniteness rejection (page 26 of the correspondence filed 4 October 2005), page 107 of the instant specification clearly defines what is meant by "a standard in vitro CRF binding assay" in the context of the instant invention.

Since the conditions of the assay are clearly defined in the specification, the Ki values thereby observed will be consistent when the assay is performed as defined in the specification. The rejection is hereby withdrawn.

Status of Claim Rejections - 35 USC § 102

In the previous Office action, claims 1, 2, 4-9 and 12-14 were rejected under 35 U.S.C. 102(a) and (e) as being anticipated by WO 01/60806 (Yoon et al).

In view of the amendment of 4 October 2005, which limits compounds according to the instant claims to pyrazine-pyridine or pyrazine-pyrimidine compounds, to the exclusion of pyrazine-phenyl compounds, the rejection under 35 U.S.C. 102 based on Yoon et al is hereby withdrawn.

Status of Claim Rejections - 35 USC § 103

In the previous Office action, claims 10 and 11 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/60806 (Yoon et al).

In view of the amendment of 4 October 2005, which excludes pyrazine-phenyl compounds as are taught by Yoon et al, the rejection is hereby withdrawn.

In the previous Office action, claims 1 and 2 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/38174 (Cox et al).

Cox et al only teaches pyrazine-phenyl compounds, so the amendment of 4 October 2005, has overcome the rejection based on Cox et al, and that rejection is hereby withdrawn.

Specification

In the previous Office action, the abstract of the disclosure was objected to as being not accurately descriptive of the invention. In view of the new, amended abstract, this objection is withdrawn.

Allowable Subject Matter

Claims 1, 2, 5-15, 17-19 and 26 are allowed.

All previously stated objections and rejections have been overcome by argument or amendment (as explained above). The closest prior art disclosures are the Yoon et al and Cox et al references, which were cited as grounds for rejection of the instant claims under 35 U.S.C. 102 and 103.

Rejoined subject matter is deemed enabled, specifically the pharmaceutical composition according to claim 17 and 18, and the package of claim 19, as well as the method according to claim 15. At the time the invention was made (the U.S. provisional application upon which the instant application is based was filed in 2002), established utilities for CRF receptor antagonists included anxiety and depression, and treatment of drug and alcohol withdrawal symptoms (not claimed). This is borne out by the two references supplied by the examiner with the Office action of 6 July 2005 (one of which is co-authored by one of the co-inventors named in this application), showing the state of the art at the time the invention was made with respect to therapeutic application of CRF receptor antagonists. Treatment of irritable bowel syndrome and Crohn's disease were not established as a therapeutically viable mode of employing CRF receptor antagonists until 2004, two years after the invention was made (as shown by the 3 references provided by applicants with the correspondence filed 9 November 2005). In 2002, only a tenuous and putative connection between the pharmacological activity of the instantly claimed compounds and the treatment of irritable bowel syndrome and Crohn's disease was known.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

All Post-Allowance Correspondence concerning this application must be mailed to:

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Or you can fax them to the Office of Patent Publications at 703-872-9306, in order to expedite the handling of such correspondence as amendments under 37 CFR 1.312; information disclosure statements, and formal drawings. Sending Post-Allowance papers to Technology Center 1600 will only cause delays in matching papers with the case.

For information concerning status of correspondence sent after receipt of the Notice of Allowance, please contact the Correspondence Branch at (703) 305-8027. The Notice of Allowance also has an insert containing contact information on other items, including Issue Fees, receipt of formal drawings and the status of the application.

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JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600